

REMARKS

Claims 1-26 are in the case. Claims 7-15, 18, 25 and 26 stand withdrawn from consideration.

Claims 1-6, 16, 17 and 19-24 stand rejected solely under 35 U.S.C. § 102(b), as allegedly anticipated by Zhao et al. (Biopharmaceutics and Drug Disposition, (1997); (18)9:769-777). This rejection is respectfully traversed.

It is well established that a single reference can only establish a *prima facie* case of anticipation if the reference enables one of ordinary skill in the art to practice the claimed invention without undue experimentation. See, e.g., Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc., 545 F.3d 1312, 1315 (Fed. Cir. 2008), and the precedents cited therein. If the cited reference fails to enable the claimed invention, it is not a valid anticipatory reference. *Id.*, at 1315-1316.

Zhao et al. is not enabling of the present invention, because it is completely devoid of any mention, hint or suggestion of the condition being treated by the presently claimed invention, and in no way suggests that the composition described in Zhao et al. could or should be used for the treatment of graying of scalp hair, or that the composition should be administered to anyone because he or she presents that condition. There are no examples or other information in Zhao et al. which would suggest that any patient population, regardless of age, could be treated for graying of scalp hair by administration of the subject composition. There is no disclosure in Zhao et al. about whether the 12 patients classified as elderly did or did not have gray hair. In fact, Zhao et al. concludes that age plays little or no factor in determining dosage for montelukast, from a pharmacokinetic point of view. See Zhao et al. at pg. 777. If anything, this would appear to teach away from the presently claimed invention, if one assumes that the graying of scalp hair is correlated with age. In essence, there is no way that Zhao et al. could be considered to enable the practice of the presently claimed invention.

Thus, the sole reference cited in support of this rejection is not a valid anticipatory reference and fails to support a *prima facie* case of anticipation. Reconsideration and withdrawal of the rejection is requested.

Favorable action on all of the pending claims is solicited. If any matter remains unresolved which may be resolved without the need for a formal action, the Examiner is invited to contact the undersigned.

Respectfully submitted,
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